AMENDMENT UNDER 37 C.F.R. § 1.111

U.S. Application No.: 09/509,681

Our Ref.: Q58461 Art Unit: 1615

6. (Twice Amended) A process according to claim 1, characterized in that the oxidation is performed by means of a hypochlorite in basic aqueous solution.

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7. (Twice Amended) A process according to claim 1, characterized in the following steps:

preparing an aqueous solution comprising the hydrogenated and oxidized dextran and at least one water-soluble ferric salt;

adjusting the pH of said aqueous solution to a value above 10 by addition of a base; heating the mixture to a temperature above 100°C until it turns into a black or dark brown collodial solution and is filterable through a 0.45 µm filter; and

purification and stabilization of the solution using filtration, heating and membrane separations and addition of one or more stabilizers.

- 8. (Amended) A process according to claim 7, characterized in that the stabilization comprises addition of at least one salt of an organic hydroxy acid.
- 10. (Twice Amended) Iron-dextran compound produced according to claim 1, characterized in that its apparent peak molecular weight (Mp) is 50.000-150.000 Da and its iron content is 15-45% b.w.

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14. (Amended) A pharmaceutical composition according to claim 13, further comprising a salt of an organic hydroxy acid as stabilizer.

15. (Amended) Use of an iron-dextran compound according to claim 10, for preparation of a parenterally administrable therapeutical composition for prophylaxis or treatment of iron-deficiency, comprising the following steps:

providing the iron-dextran compound as an aqueous solution; and sterilizing the composition.

16. (Amended) Use of a dextran preparation obtainable by a process according to claim 9, for the production of an iron-dextran compound in a process comprising the following steps:

mixing the dextran preparation as an aqueous solution with at least one water soluble ferric salt;

heating the mixture to a temperature above 100 C until said mixture turns into a colloidal solution that can be filtered through a 0.45 μm filter; and

purification of the solution.

Please add the following new claims:

17. (New) The process for producing a dextran preparation according to claim 9, wherein the dextran has a molecular weight less than 7,000 Daltons.

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18. (New) The process for producing a dextran preparation according to claim 17, wherein the dextran is purified by one or more membrane separations having a cut-off value suitable for holding back dextran molecules above 2,700 Daltons.

19. (New) The process for producing a dextran preparation according to claim 18, wherein the process further comprises further hydrolysis, and one or more separations having a cut-off value between 340 and 800 Daltons removing the smaller molecules.

20. (New) The process for producing a dextran preparation according to claim 9, wherein the dextran preparation has a reduced sugar content not above 4% b.w. after the oxidation.

21. (New) The process for producing a dextran preparation according to claim 9, wherein the hydrogenation is performed by means of sodium borohydride in aqueous solution.

22. (New) The process for producing a dextran preparation according to claim 9, wherein the oxidation is performed by means of a hypochlorite in basic aqueous solution.

23. (New) The process for producing a dextran preparation according to claim 22, wherein the hypochlorite is sodium hypochlorite.

- 24. (New) The process according to claim 3, followed by further hydrolysis and one or more membrane separations having a cut-off value between 340 and 800 Da removing the smaller molecules.
- 25. (New) A process according to claim 1, characterized in that the oxidation is performed by means of a sodium hypochlorite in basic aqueous solution.
- 26. (New) A process according to claim 7, further comprising drying the solution to obtain the desired iron-dextran compound as a stable powder.
- 27. (New) A process according to claim 7, characterized in that the stabilization comprises addition of at least one salt of an organic hydroxy acid selected from the group comprising citrates and gluconates.
- 28. (New) A pharmaceutical composition according to claim 13, further comprising a salt of an organic hydroxy acid selected from the group comprising citrates and gluconates as stabilizer.

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29. (New) Iron-dextran compound produced according to claim 1, characterized in that its apparent peak molecular weight (Mp) is 70.000-130.000 Da and its iron content is 15-45% b.w.

30. (New) Iron-dextran compound produced according to claim 1, characterized in that its apparent peak molecular weight (Mp) is 80.000-120.000 Da and its iron content is 15-45% b.w.

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31. (New) Use of an iron-dextran compound according to claim 15, further comprising adding salt of an organic hydroxy acid to said compound.

- 32. (New) Use of an iron-dextran compound according to claim 15, further comprising adjusting the iron content of the compound through the addition of water.
- 33. (New) Use of a dextran preparation according to claim 16, further comprising drying the solution to obtain the iron-dextran compound as a stable powder.